

## Chlorendic Anhydride - Comments of Environmental Defense

(Submitted via Internet 7/1/02)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for Chlorendic Anhydride (CAS# 115-27-5).

In general, we agree with the sponsor's conclusion that no additional testing is required for HPV purposes. We do have one potential concern about the adequacy of the data with regard to reproductive toxicity.

Specifically, in our view examination of the reproductive organs following a repeat-dose study is not really an adequate assessment of reproductive toxicity. However, we recognize that the SIDS program guidelines state that "when a 90-day repeated dose study is available and demonstrates no effect on reproductive organs, in particular the testes, then a developmental study ... can be considered as an adequate test to complete information on reproduction/developmental effect." As a result, we concur that no additional reproductive testing is required under the HPV program.

We have one additional minor comment. As anticipated, chlorendic anhydride rapidly hydrolyzes to chlorendic acid in any aqueous environment. Thus, it technically degrades very rapidly in the environment. However, it is seen in the Robust Summary that chlorendic acid did not degrade at all on incubation with activated sludge for 30 days. Thus, the Test Plan should note that release of chlorendic anhydride into the environment could result in environment persistence and possible bioaccumulation of chlorendic acid.

Finally, we note that the format of this test plan/robust summary differs from that used by many other sponsors, in that it consists only of a table summarizing data availability/testing needed for the SIDS endpoints, together with a Robust Summary of one study per endpoint. It is not clear if other data are available, and if so, what they show. EPA's Guidance on Robust Summaries states that "A complete robust study summary should be prepared for at least one key or critical study for each SIDS endpoint that has been considered adequate according to EPA guidance. Robust summaries may also be prepared for other adequate studies that are considered supportive of the key study. . . . In addition, a single "best" study would contain a weight-of-the-evidence analysis in its remarks section (see below) which refers to, and ties together, the other studies." <http://www.epa.gov/chemrtk/robsumgd.htm>. Even if the test plan/robust summary for chlorendic anhydride technically meets minimum requirements of the HPV initiative (and it is not clear to us whether it does), it is far less informative than the submissions made by many other sponsors.

Thank you for this opportunity to comment.

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